IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**No. 1:19-md-2875-RBK** **Hon. Robert Kugler** **Jury Trial Demanded**

THIRD-PARTY PAYORS' BRIEF IN SUPPORT OF MOTION TO CERTIFY CLASS

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INTRODUCTION

Third-Party Payors MSP Recovery Claims, Series LLC ("MSPRC") and Maine Automobile Dealers Association, Inc. Insurance Trust ("MADA") (together, "TPP Plaintiffs"), on behalf of themselves and the proposed Classes of Third-Party Payors ("TPPs"), move for certification of damages Classes pursuant to Fed. R. Civ. P. 23(b)(3). The TPPs allege, on behalf of themselves and the Classes, that Defendants violated state consumer protection laws and the common law by marketing and selling valsartan-containing drugs ("VCDs") that were contaminated with cancer-causing nitrosamine impurities. These contaminated VCDs, which have been and remain the subject of one of the largest contaminated-drug recalls, were designed, manufactured, labeled, marketed, distributed, packaged, and sold by Defendants, and were adulterated, misbranded, unapproved, and illegal to distribute or sell in the U.S. This caused TPP Plaintiffs and the Class they represent monetary harm.

FACTUAL BACKGROUND[1]

Both valsartan RLDs and generic versions are prescription-only drugs. In most instances, a patient's prescription is covered (in whole or in part) by a TPP health plan. TPPs thus bear the brunt of the cost of these generic valsartan drugs. Specifically, TPPs paid or made reimbursements for Defendants' contaminated, adulterated, misbranded, and/or unapproved VCDs that were illegally manufactured, sold, designed, packaged, labeled, marketed, and

[1] TPP Plaintiffs incorporate by reference and do not repeat all of the contents of the Consumer Plaintiffs' brief on class certification (Consumer Brief). TPP Plaintiffs submit as Exhibit 3 the Expert Report of Kali Panagos, Pharm.D., R.Ph. (Panagos Report). TPP Plaintiffs also rely on two expert reports submitted with the Consumer Brief: The Declaration of Laura R. Craft (Craft Decl.); and the Declaration of Rena Conti, Ph.D. ("Conti Decl.").

distributed in the United States as generic and bioequivalent versions of DIOVAN, DIOVAN HCT, EXFORGE, and EXFORGE HCT.

Defendants' generic VCDs (1) were, in fact, not U.S. Food and Drug Administration ("FDA") approved generic versions of these drugs, (2) did not meet the quality standards or match the ingredients listed on their labels and package inserts, (3) did not satisfy the criteria to be accurately described as generic equivalents, and (4) did not meet the applicable USP and Orange Book standards,[2] but instead (5) were of a lesser quality and were adulterated and/or misbranded (and thereby rendered worthless) by contamination with EPA-listed probable human carcinogens known as N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA"). TPPs thus paid or made reimbursements for generic VCDs that were illegally and willfully introduced into the market by Defendants, causing TPPs to sustain economic damages.

Third-Party Payors' Role in the Pharmaceutical Supply Chain

TPPs are health care benefit providers, such as an employer's insurance company or a health and welfare plan providing health care benefit to employees or beneficiaries. TPPs pay in whole or in part for the VCDs at issue in this case.

Plaintiff MADA is a multiple employer welfare benefit plan or arrangement that provides health benefits, including prescription drug coverage, to the employees of multiple employers and to their beneficiaries. MADA's members received prescriptions for, and MADA paid for, VCDs listed as recalled by the FDA that were manufactured, distributed, or sold by at least the

[2] Conti Decl., at ¶38 ("[C]ompliance and assurance that their products meet *at minimum* all applicable safety and quality laws and regulations governing the sale of FDA approved prescription drugs is essential to a generic drug product's listing in the Orange Book; indeed, it is essential to the very status of generic drugs, including the at-issue Valsartan products, as generic.") (footnote omitted).

ZHP/Solco, Hetero/Camber, Mylan, Aurobindo, Teva/Actavis, and Torrent Defendants. MADA made payments on behalf of members in Maine, Florida, and New Jersey.

Summacare, Inc. ("Summacare"), Group Health Plan, Inc. and Health Insurance Plan of Greater New York (collectively, "Emblem"), and Connecticare, Inc. are health plans which have executed irrevocable assignments of any and all rights to recover payments made on behalf of their health plan members and enrollees under Medicare Parts A, B, and D to certain series of Plaintiff MSPRC. These assignments authorize these series and, in turn, MSPRC through its operating agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and Medicare benefits. Specifically, MSRPC's assignors paid millions of dollars for generic valsartan drugs on behalf of their enrollees. MSPRC's payments include those payments for defendants' VCDs, which were also manufactured, distributed, and sold during that same period by the ZHP/Solco, Hetero/Camber, Mylan, Aurobindo, Teva/Actavis and Torrent Defendants. MSPRC's payments include payments made on behalf of beneficiaries in the following states and territories: Alabama, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, North Carolina, Nebraska, New Hampshire, New Jersey, Nevada, New York, Ohio, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Tennessee, Texas, Virginia, Vermont, Wisconsin, and West Virginia.

The pharmaceutical supply chain in the United States consists of four major sets of actors: pharmaceutical manufacturers (both active pharmaceutical ingredient and finished dose), wholesale distributors, pharmacies, and Pharmacy Benefit Managers ("PBMs"). *See* Conti Decl., at ¶¶47-54; Craft Decl., at ¶¶ 11, 16-20, 33-35, and 71; and Panagos Report, at ¶¶ 19-28 and Section VI. Pharmaceutical manufacturers produce prescription drugs, which go first to

wholesale distributors, and then on to retail or mail-order pharmacies. Pharmacies then dispense these prescription drugs to beneficiaries for consumption. Prescription drugs are processed through quality- and utilization-management screens by PBMs. TPPs, who pay for the drugs, often contract with and pay PBMs to administer their drug programs. *Id.* PBMs, acting as agents for the TPPs and their Pharmacy and Therapeutics (T&P) Committees, are tasked with developing drug formularies (lists of drugs included in coverage at various pricing "tiers"), processing claims, creating a network of retail pharmacies, and negotiating with pharmaceutical manufacturers. *Id.*

In some instances, PBMs are responsible for placing generic drugs, such as VCDs, on the TPPs' formularies. Panagos Report at ¶¶19-28, 45 and Section VI. In conducting formulary management, TPPs and their PBMs reasonably expect that generic prescription drugs listed in the Orange Book can be included in their formularies and qualify for reimbursement because they are legally compliant in terms of pharmaceutical equivalence, therapeutic equivalence, or bioequivalence or are otherwise the same as their RLD counterparts.[3] This is only made possible because of the manufacturers' and distributors' representations that their generic drugs, such as Defendants' VCDs, comply with their respective Abbreviated New Drug Applications (ANDAs)

[3] *See* Panagos Report at ¶¶29-59 and Section VI.; Declaration of Third Party Payor Humana Inc. (Humana Decl.), ¶2; *see also* Conti Decl., at ¶40 ("[T]hird-party payers continuously assess whether and which prescription drug treatments might provide their members benefit and value to treat medical conditions and symptoms. The assurance of quality manufacturing by the manufacturers of prescription drugs is foundational to third-party payers' decision making."). "In other words, in the United States prescription drug market, insurers do not monitor drug manufacturers' compliance with laws and regulations related to safety and quality; that is not their job. Instead, they presume that drug manufacturers are in compliance with all applicable laws and regulations related to safety and quality, that the drugs are not adulterated or misbranded and that the FDA and other regulatory agencies have monitored the manufacturers' efforts to ensure compliance, otherwise they would not be placed into the stream of commerce." *Id*. In sum, "[t]here is no insurer demand for non-safety and quality compliant, adulterated, and misbranded drugs." *Id*.

filed with the FDA, which state that Defendants' generic drugs are bioequivalent to their respective branded drugs. Panagos Report at ¶¶29-59 and Section VI. Thus, the TPPs permitted the VCDs to be included on their formularies based on the Defendants' misrepresentations that their VCDs were pharmaceutically equivalent, therapeutically equivalent, and bioequivalent to branded RLDs DIOVAN, DIOVAN HCT, EXFORGE, and EXFORGE HCT; satisfied all compendia, quality, purity and other requirements; complied with all cGMPs; and were safe for consumption.

Formulary Placement of Generic Equivalents

TPPs promote the appropriate use of generics, primarily through tiered formularies that assign lower co-pays or coinsurance to generic drugs as compared to their brand equivalents. By and large, TPPs' formularies treat placement of their generic equivalents very similarly. Panagos Report, ¶¶44-59 and Section VI. All states except Oklahoma have laws that either require or permit pharmacists to substitute a generic for a prescribed brand drug when an equivalent generic is available. Publicly available data on formulary status collected from payors and PBMs across the United States and its territories confirms that brand drugs only rarely receive the same or more favorable formulary tier placement and coverage as their generic equivalents. Craft Decl., ¶¶ 15, 18. Thus, formulary placement corresponds with the amount that a plan participant must contribute as a co-payment when purchasing a drug—the higher the placement, the lower the copayment, and the higher likelihood that the drug will be purchased by plan beneficiaries in lieu of a more expensive alternative, and vice versa. Higher formulary placement increases the likelihood that a doctor will prescribe the drug. TPPs provide copies of their PBMs' formularies to providers, pharmacists, and patients in their network to help prescribers adhere to the formulary. *Id*. ¶ 71. When a patient presents a prescription at a pharmacy, the drug's placement

on the TPP's formulary will determine the amount of the patient's co-payment and the TPPs' payment. *Id*. ¶¶ 15, 18. When the patient's prescription is filled, the pharmacy submits a claim to the PBMs for reimbursement. PBMs then cumulate those individual reimbursements and present them to TPPs. TPPs are the payors ultimately responsible, or at risk, for payments associated with their insureds' purchases. Panagos Report, ¶¶16 and Section VI.G; Humana Decl., ¶2; and Declaration of Margaret Finn (Finn Decl.), ¶2.

Manufacturing Process of Generic Valsartan and Subsequent Recall

The manufacturing process of generic valsartan and subsequent recall are set forth in detail in section III of the Consumer Brief. TPPs will be able to show through common proof, substantiated by expert analysis,[4] that Defendants' actions had the effect of fraudulently inducing TPPs to pay, in whole or in part, for Defendants' VCDs—products that Defendants knew or should have known were not therapeutically equivalent to their RLDs, did not comply with cGMPs, and were adulterated and misbranded. TPPs would not have paid the amounts they paid for Defendants' VCDs if they had known the truth. Panagos Report, ¶¶44-59 and Section VI. In fact, TPPs could not have paid any amounts for Defendants' VCDs if they had known the truth, because Defendants' VCDs were illegally manufactured, illegally imported, illegally distributed, and illegally sold to TPPs based on Defendants' fraudulent misrepresentations and omissions.

ARGUMENT

I. Numerous Courts Have Certified TPP Litigation Classes.

Courts have repeatedly certified litigation classes of TPPs and consumers advancing the same claims arising from the same unlawful conduct of a defendant, recognizing that TPP class

[4] *See generally*, Conti Decl.; Panagos Report; and Craft Decl.

members have suffered the same economic injuries as consumers. For example, the *In re EpiPen* court certified classes of consumers and TPPs challenging a decision by the manufacturer of EpiPens not to sell the product in single packages. *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig*., 2020 WL 1873989, at *3 (D. Kan. Feb. 27, 2020) ("Plaintiffs . . . allege that [this] forced consumers and third-party payors to overpay for the EpiPen 2-Pak because the switch effectively doubled the EpiPen's price."). Rejecting the argument that "the alleged conflict between consumers and third-party payors precludes class certification," the Court observed that "consumers and third-party payors share an 'alignment of incentives' because they both seek to prove that defendants' illegal conduct caused them to sustain injuries in the form of overpaying for the EpiPen." *Id*. at *21.

In re Cardizem CD Antitrust Litig., 200 F.R.D. 326 (E.D. Mich. 2001), was an antitrust action alleging that defendants had conspired to delay generic competition. The district court certified a class that included "consumers (both cash payers and those with prescription drug coverage) and third-party health care benefit providers (such as managed care organizations, self-funded employers, and government programs like Medicaid) who have paid all or part of the supra-competitive prices consumer class members claim they were charged for their Cardizem CD and Cartia XT prescriptions . . . ." *Id*. at 332. Like the *EpiPen* court, the *Cardizem* court rejected the argument that the interests of consumer and TPPs were in conflict, reasoning that "[e]ach class member has the same interest in maximizing the aggregate amount of classwide damages." *Id*. at 337 (quotation marks omitted). The court also rejected the defendant's theory that "third-party payer class members failed to mitigate their damages or passed-on any overcharges they may have incurred as a result of Defendants illegal conduct," explaining that

"the presence of individualized defenses, such as mitigation, going only to damages are generally regarded as no barrier to class certification." *Id*. at 347 (quotation marks omitted).

In re Terazosin Hydrochloride, 220 F.R.D. 672 (S.D. Fla. 2004) is to the same effect. That court certified classes of consumers and TPPs suing drug manufacturers for antitrust violations based on delaying the emergence of generic competition. *Id*. at 680 ("Indirect Purchaser Plaintiffs have demonstrated the requisite nexus between the claims of the third-party payers and the individual consumers," and "no conflicts exist between the two types of end payers that would preclude class certification."). The court noted that "while the third-party payer class members may be financially able to assert their own claims in separate actions, the fact that the same allegedly anticompetitive conduct gives rise to each class member's economic injury makes it highly desirable to concentrate litigation of their claims in this forum." *Id*. at 700 (citing *In re Synthroid Marketing Litig*., 188 F.R.D. 287, 295–96 (N.D. Ill. 1999)); *accord In re Cardizem*, 200 F.R.D. at 351 ("[T]he . . . Rule 23(b)(3) class action was designed not solely as a means for assuring legal assistance in the vindication of small claims but[] rather to achieve the economies of time, effort, and expense.") (quotation marks omitted).

In another delayed generic competition case, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig*., No. CV 14-MD-02503, 2017 WL 4621777, at *1 (D. Mass. Oct. 16, 2017), the court certified classes of consumers and TPPs, rejecting (among other theories) the defendants' argument that the TPPs were "uninjured because they would have recouped the costs of overcharges through higher premiums or co-pay amounts." *Id*. at *18. The court reasoned that "even to the extent that institutional payors can offset overcharges through later increases in premiums, the institutional payors experienced antitrust impact at the time of the initial overcharge." *Id*. The court also rejected a challenge to the "adequacy of representation" based on

concern that "third-party insurers and consumers are two fundamentally different groups," noting that "[t]his argument has been rejected by this Court and others certifying end-payor classes consisting of both consumers and third-party purchasers." *Id*. at *12; *accord In re Ranbaxy Generic Drug Application Antitrust Litig*., 338 F.R.D. 294, 305 (D. Mass. 2021) (certifying classes "comprised of thousands of TPPs who paid for prescriptions of the subject drugs" and who claimed defendants had delayed generic competition).

Many courts have certified classes of TPPs.[5] The Third Circuit also has affirmed the certification of a TPP settlement class. *In re Warfarin Sodium Antitrust Litig*., 391 F.3d 516, 531

[5] *See In re Lidoderm Antitrust Litig*., No. 14-MD-02521-WHO, 2017 WL 679367, at *5 (N.D. Cal. Feb. 21, 2017) ("Plan sponsors who pay for prescriptions are TPPs and included in the EPP class."); *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig*., 335 F.R.D. 1, 10 (E.D.N.Y. 2020) (court certified class alleging drug manufacturers' conspiracy to suppress generic competition that "includes insured consumers, uninsured consumers ('cash payors'), and third-party payors ('TPPs'). TPPs are entities that pay or provide reimbursement for all or some of the cost of a drug for people whom they insure."); *In Sheet Metal Workers Loc. No. 20 Welfare & Benefit Fund v. CVS Pharmacy, Inc*., No. CV 16-046 WES, 2021 WL 1986564 (D.R.I. May 18, 2021) (certifying class of TPPs alleging that defendants fraudulently reported an inflated usual and customary price for generic drugs); *In re Flonase Antitrust Litig*., 284 F.R.D. 207, 210 (E.D. Pa. 2012) (certifying class of consumers and TPPs alleging that the defendant manufacturer "filed sham citizen petitions with the Food and Drug Administration . . . to delay the entry of a cheaper, generic version of Flonase into the market."); *New England Carpenters Health Benefits Fund v. First DataBank, Inc*., 248 F.R.D. 363, 364 (D. Mass. 2008) (certifying class of consumers and TPPs alleging that defendants "engaged in a racketeering enterprise . . . to fraudulently state the 'average wholesale price' . . . for numerous prescription pharmaceuticals . . . ."); *In re Loestrin 24 FE Antitrust Litig*., 410 F. Supp. 3d 352, 366 (D.R.I. 2019) (certifying class of TPPs and consumers alleging that defendant "committed fraud on the Patent and Trademark Office in enforcing the patent for Loestrin 24 and filing sham litigation against potential generic competitors."); *In re Synthroid Mktg. Litig*., 188 F.R.D. 287, 289 (N.D. Ill. 1999) (certifying class of TPPs "alleging federal and state claims relating to the marketing and sale of the drug Synthroid."); *In re Relafen Antitrust Litig*., 221 F.R.D. 260, 271 (D. Mass. 2004) (certifying, in antitrust class action, classes that "expressly include insurers as 'third-party payors'"); *In re Pennsylvania Baycol Third-Party Payor Litig*., No. 1874 SEPT. TERM 2001, 2005 WL 852135, at *8 (Pa. Com. Pl. Apr. 4, 2005) ("The named plaintiffs are typical of those class claimants for both the warranty and unjust enrichment claims since they made payments on behalf of individuals who purchased Baycol but were advised by the defendant . . . to cease taking the medication and have incurred additional, otherwise unnecessary costs, when their insureds were told not to use the medication.").

(3d Cir. 2004) ("TPPs, like individual consumers, suffered direct economic harm when, as a result of DuPont's alleged misrepresentations, they paid supracompetitive prices for Coumadin instead of purchasing lower-priced generic warfarin sodium.").

These cases demonstrate that certification of a class of TPPs is appropriate where, as here, the TPPs all suffered the same economic injuries arising from the defendants' unlawful marketing, distribution, and sale of contaminated drugs.

II. The Requirements of Rule 23 Are Met.

A. Class Certification Standard

As set forth in detail in section IV of the Consumer Brief, a "rigorous" analysis will show the requirements of Rule 23(a) and 23(b) have been met. *Amgen Inc. v. Connecticut Ret. Plans & Tr. Funds*, 568 U.S. 455, 465 (2013) (quoting *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 351 (2011)); *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013). Specifically, Rule 23(a) requires that "(1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class." Rule 23(b)(3), which applies here, requires that "questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Plaintiffs must satisfy the requirements of Rule 23 by a preponderance of the evidence. Fed. R. Civ. P. 23; *In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184, 192 (3d Cir. 2020).

B. The requirements of Rule 23(a) are met.

1. The proposed Class is so numerous that joinder is impracticable.

In order to meet the first requirement of Rule 23(a), "numerosity," Plaintiffs must demonstrate that "the [proposed] class is so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). "To meet the impracticability standard, a party need not prove that joinder of every class member is impossible; instead, proof of 'difficulty or inconvenience of joining all members of the class' suffices." *Weisfeld v. Sun Chem. Corp.*, 210 F.R.D. 136, 139 (D.N.J. 2002) (quoting *Harris v. Palm Springs Alpine Estates, Inc.*, 329 F.2d 909, 913-14 (9th Cir. 1964)). "No minimum number of plaintiffs is required to maintain a suit as a class action, but generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met." *Stewart v. Abraham*, 275 F.3d 220, 226-27 (3d Cir. 2001). Because there are thousands of TPPs nationwide, the Class members are so numerous that joinder of all members is impracticable. Craft Decl., ¶¶14, 72.

2. TPP Plaintiffs' claims present common issues of law and fact.

The second of the four criteria for class certification under Rule 23(a), "commonality," requires Plaintiffs to demonstrate that "there are questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). *See* Consumer Brief at 61–62.

In cases like this one, where the Class is alleging liability based on the defendants' deception, fraud or omissions, commonality is satisfied because the focus of the litigation is centered on defendant's conduct, which is an issue common to all class members. *See In re Cmty. Bank of N. Virginia Mortgage Lending Practices Litig.*, 795 F.3d 380, 399 (3d Cir. 2015); *Sullivan v. DB Investments*, 667 F.3d 273, 299 (3d Cir. 2011). Because the requirement may be satisfied by a single common issue, Defendants cannot credibly argue that the commonality

requirement has not been satisfied. *See Baby Neal by Kanter v. Casey*, 43 F.3d 48, 56 (3d Cir. 1994).

Here, many key questions of law or fact are common to the proposed classes. As detailed in the Third Amended Consolidated Economic Loss Class Action Complaint, p. 187, ¶ 614, ECF No. 1708, key questions of law or fact that are common to the Class include:

- Whether each Defendant made express or implied warranties of "sameness" to TPP Plaintiffs and Class Members regarding their generic VCDs;
- Whether each Defendant's VCDS were in fact the same as their RLDs consistent with such express or implied warranties;
- Whether each Defendant's VCDs were contaminated with NDMA, NDEA, or similar contaminants;
- Whether each Defendant's VCDs containing NMDA, NDEA, or similar contaminants were adulterated and/or misbranded;
- Whether Defendants violated cGMPs regarding the manufacture of their VCDs;
- Whether each Defendant falsely claimed that its VCDs were the same as their RLDs and thus therapeutically interchangeable;
- Whether each Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs;
- Whether TPP Plaintiffs and other Class Members have been injured as a result of each Defendant's unlawful conduct, and the amount of their damages;
- Whether a common damages model can calculate damages on a class-wide basis;
- When TPP Plaintiffs' and Class Members' causes of action accrued; and
- Whether Defendants fraudulently concealed TPP Plaintiffs' and Class Members' causes of action.

Doc. 1148-3, ¶ 616. Each of these common questions can be resolved with class-wide evidence. Thus, the Class satisfies Rule 23(a)(2).

3. TPP Plaintiffs' claims are typical of those of the Class.

Rule 23(a)(3) requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). This requirement ensures that the interests of named plaintiffs are aligned with the interests of the absent members. The typicality requirement of Rule 23 does not mean that the claims of each Class member must be identical. *See Suchanek v. Sturm Foods, Inc.*, 311 F.R.D. 239, 255-56 (N.D. Ill. 2015).

Here, the named TPP Plaintiffs' and the Class' claims arise from the same course of conduct: Defendants' manufacturing, labelling, marketing, distributing, packaging, and/or selling VCDs that were contaminated with nitrosamine impurities. This conduct caused the named TPP Plaintiffs and the Class to suffer the same type of economic harm: paying for worthless valsartan. All TPPs, including the named TPP Plaintiffs, made payments and/or reimbursements for generic VCDs that were illegally introduced into the market by Defendants, causing all TPPs to sustain economic damages. The claims are based on common causes of action of unjust enrichment, breach of express and implied warranties, fraud, and violation of state consumer protection laws.

The fact that the claims arise under multiple state laws does not defeat typicality where, as here, the relevant state laws mirror each other in their essential elements.[6] The named TPP Plaintiffs have substantially the same interest as all other Class Members, and their claims arise out of the same set of facts as the claims of all other Class Members. Rule 23(a)(3) is satisfied.

4. TPP Plaintiffs will fairly and adequately represent the class.

Rule 23(a)(4) requires that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). "The adequacy inquiry . . . serves to uncover

[6] Plaintiffs have compiled the applicable state consumer protection statutes and common law and the cases describing their similarities in Exhibit 2 to the Consumer Brief. Attached as Exhibit 9 is the Table of TPP Consumer Law Claims.

conflicts of interest between named parties and the class they seek to represent." *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 625 (1997). "For a conflict of interest to prevent plaintiffs from meeting the requirement of Rule 23(a), that conflict 'must be fundamental. It must go to the heart of the litigation.'" *Gunnells v. Healthplan Servs., Inc.* 348 F.3d 417, 430-31 (4th Cir. 2003) (quoting 6 Alba Conte & Herbert B. Newberg, *Newberg on Class Actions* Section 18:14 (4th ed. 2002)). *See also* Consumer Brief at 64–65.

There is no apparent conflict between the interests of the named TPP Plaintiffs and the rest of the class. To the contrary, as discussed above with respect to Rule 23(a)'s typicality requirement, the named Plaintiffs suffered the same harm as other Class Members and have the same interest in quickly and efficiently redressing that harm. Plaintiffs' claims are co-extensive with those of members of the proposed classes. All assert the same legal claims, and all seek identical relief. Where, as here, the overarching question posed by the claims is based on Defendants' conduct, named TPP Plaintiffs and the Class have the same objective: proving that Defendants acted unlawfully and that TPPs were harmed economically as a result.

TPP Plaintiffs have retained counsel who are experienced in pharmaceutical and consumer fraud litigation, class actions, and federal court litigation. TPP Plaintiffs and their counsel have vigorously litigated this case and will continue to do so. TPP Plaintiffs' claims are consistent with, and not antagonistic to, those of the other Class Members they seek to represent. TPP Plaintiffs have searched for and produced documents, completed TPP Plaintiff Fact Sheets, given depositions, and otherwise responsibly and adequately discharged their duties as class representatives. TPP Plaintiff MSPRC's similar affiliate, MSPA Claims 1, LLC, was recently certified as a class representative in MSPA Claims 1, LLC v. IDS Prop. Cas. Ins. Co., Case No. 2015-027940-CA-01, slip op. at 23 (Fla. 11th Cir. Ct. Aug. 6, 2021). TPP Plaintiffs have no

disabling conflicts with Class Members and will fairly and adequately represent their interests. Rule 23(a)(4) is therefore satisfied.

5. The Class is definite and ascertainable.

Along with the four explicit requirements of Rule 23(a), the Third Circuit recognizes an implied requirement of ascertainability that is distinct from the predominance requirement. *See Byrd v. Aaron's Inc.*, 784 F.3d 154, 161–64 (3d Cir. 2015). *See* Consumer Brief at 55–60 and 68-69. However, TPP Plaintiffs "need not, at the class certification stage, demonstrate that a single record, or set of records, conclusively establishes class membership." *City Select Auto Sales Inc. v. BMW Bank of N. Am. Inc.*, 867 F.3d 434, 441 (3d Cir. 2017).

The Class definitions meet this requirement. Pharmaceutical transactions are some of the most detailed and well-documented in any industry, with almost every aspect recorded in uniform data outputs. Data exist to trace and confirm the sale or purchase of valsartan and various valsartan containing drugs (collectively "VCDs") throughout the U.S. supply chain.[7] By referencing readily available, detailed data sources used in the data-rich pharmaceutical industry, TPPs can identify Class Members by reference to the objective criteria in the class definition.

Subject to certain exclusions, each definition defines a class member as an entity that paid for part or all of the purchase price of a VCD during a specific date range: since at least January 1, 2012 through the date of final recall as of November 10, 2021. Using one or more of the layers of detailed purchase data that are readily available from PBMs and pharmacies, TPP Plaintiffs can reliably identify Class Members by reference to the objective criteria in the class definition: (i) TPP purchases of Valsartan, not for resale; (ii) in applicable states; (iii) during a

[7] Craft Decl., at ¶8; Humana Decl., ¶¶3-6; and Finn Decl., ¶¶3-6.

discrete time period.[8] TPP Plaintiffs' expert Laura Craft explains that detailed, transaction-level pharmaceutical industry data exist to identify Class Members: the types of data exist and can be used to identify which consumers and TPPs paid for which VCDs, and, more importantly, to apportion the market of VCDs by each manufacturer, wholesaler, and retail pharmacy, over time in an objective, administratively feasible manner. Absent access to these data, it would be significantly more time-consuming, expensive, and challenging to apportion the market of VCDs sold over time by each manufacturer, wholesaler and retail pharmacy. Craft Decl., ¶¶ 8–13; *see generally* Craft Decl.

All or nearly all of the industry data necessary to identify Class membership are conveniently concentrated among a handful of PBMs, who maintain detailed purchase data on prescription drug claims, including payment amounts, coverage, and plan characteristics. The top PBMs confirm that they maintain this readily accessible data in an industry standard format that can identify every TPP that has purchased a drug. Moreover, the data are maintained in an electronic format using standardized fields. Electronic PBM data have been used in other cases to identify class members and can easily be merged, standardized, and reviewed to identify Class Members and details of their VCD purchases and purchases of replacement drugs in this case.

[8] All of TPPs' proposed class definitions exclude the following:

> Excluded from all of TPPs' proposed class definitions are the following: (a) Defendants and affiliated entities; (b) Defendants' assigns, and successors; (c) All federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (d) Pharmacy Benefit Managers ("PBMs"); (e) TPPs whose only valsartan-containing drug purchases, who would otherwise meet this Class Definition, were for Hetero Defendants' valsartan-containing drugs dispensed prior May 1, 2018; and (f) All third-party payors who properly execute and file a timely request for exclusion from any Court-approved class.

Other federal courts analyzing similar classes have found the ascertainability requirement satisfied through methods similar to the method proposed here. Based on the layers of purchase information in this industry and the methods available to use the information to identify class members, TPP Plaintiffs have established that the Class is ascertainable.

C. Proposed TPP Class Counsel Meet the Requirements of Rule 23(g).

Rule 23(g) sets forth the following criteria for a court to consider in appointing class counsel: "(i) the work counsel has done in identifying or investigating potential claims in the action; (ii) counsel's experience in handling class actions, other complex litigation, and the types of claims asserted in the action; (iii) counsel's knowledge of the applicable law; and (iv) the resources that counsel will commit to representing the class." Fed. R. Civ. P. 23(g).

In addition to the MDL leadership of Co-Lead Counsel, attorneys representing the TPP class throughout this litigation seek appointment as class counsel of Gregory Hansel, Preti Flaherty Beliveau & Pachios, Chartered, LLP, Counsel for MADA; and Jorge Mestre, Rivero Mestre LLP, Counsel for MSPRC. Hansel and Mestre have worked with other associated counsel since the inception of this case to investigate TPPs' claims and prepare for class certification and trial. This work has included: (1) review and organization of documents produced by various Defendants and third parties, as well as TPPs' own documents for production to defense counsel; (2) pursuing discovery from defendants and third parties; (3) meeting and conferring with defense counsel on discovery matters; (4) preparing and defending their designees for depositions; (5) engaging in motion practice; and (6) researching, retaining, and working with experts to support class certification and proof of class claims and damages at trial. *See* Declaration of Gregory Hansel, Ex. 6 and Declaration of Jorge Mestre, Ex. 7. These efforts demonstrate counsel's qualifications and commitment to the TPP Class they represent.

D. The requirements of Rule 23(b)(3) are met.

In addition to meeting the four criteria of Rule 23(a), Plaintiffs must also demonstrate that their proposed class action falls within one of the three categories enumerated in Rule 23(b). *Baby Neal*, 43 F.3d at 55.

1. Common issues predominate across TPP Plaintiffs' claims.

The predominance inquiry "tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Amchem*, 521 U.S. at 623. "Issues common to the class must predominate over individual issues." *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311 (3d Cir. 2008) (quotation marks omitted). This does not mean that plaintiffs must "prove that each elemen[t] of [their] claim [is] susceptible to classwide proof," but just that "common questions *predominate* over any questions affecting only individual [class] members." *Amgen*, 568 U.S. at 469 (2013) (quotation marks omitted). If common issues are found to predominate as to liability, "individual damages allocation issues are insufficient to defeat class certification." *In re Flonase Antitrust Litig*., 284 F.R.D. 207, 233 (E.D. Pa. 2012) (quotation marks omitted).

"[G]ranular uniformity between class members is not required for establishing predominance." *Rivet v. Off. Depot, Inc.*, 207 F. Supp. 3d 417, 431 (D.N.J. 2016). Thus, a "fatal similarity—[an alleged] failure of proof as to an element of the plaintiffs' cause of action"—is not a bar to class certification. *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 457 (2016); *Harnish v. Widener Univ. Law School*, 883 F.3d 298, 305 (3d Cir. 2016) ("[E]vidence as to an issue or element need not be produced at class certification where the very nature of the issue or element guarantees that all class members' claims will 'prevail or fail in unison,' and therefore there is 'no risk whatever that a failure of proof on the common question . . . will result in

individual questions predominating.'") (quoting *Amgen, Inc*., 568 U.S. at 460, 467–68). "[P]redominance is a test readily met in certain cases alleging consumer . . . fraud," because typically "the focus is on whether the defendant's conduct was common as to all of the class members, not on whether each plaintiff has a colorable claim." *Reyes v. Netdeposit, LLC*, 802 F.3d 469, 488–89 (3d Cir. 2015)(quotation marks omitted)TPP Plaintiffs allege that Defendants were unjustly enriched at the expense of TPP Plaintiffs and other Class Members by the virtue of TPPs paying for the Defendants' VCDs. Common issues include: (1) how much the TPPs paid for VCDs; (2) the profit, benefit, and other compensation to Defendants as a result of the TPPs' payments for VCDs; (3) the value of the VCDs that TPPs paid for and whether they were in fact worthless; and (4) whether it would be inequitable and unconscionable for Defendants to retain the profit, benefit, and other compensation from TPP Plaintiffs and other Class Members from the sale of these VCDs. These common issues lie at the heart of this litigation and predominate over any individualized issues that exist.

The generic elements of an express warranty claim are common across all states, with certain variations discussed below. Those elements are: (1) the existence of an express warranty; (2) breach of that warranty; (3) proximate causation; and (4) damages. TPP Plaintiffs also allege that they relied on the express warranties of manufacturer Defendants that a generic medication is equivalent to a listed medication. They further allege that by introducing their respective VCDs in the United States as a therapeutic equivalent to their RLDs, USP designated, and with the FDA-approved label that is the same as that of the RLDs, Defendants represented and warranted to TPPs that their VCDs were in fact the same as, and were therapeutically interchangeable with, their RLDs. Doc. 1148-3, ¶ 418; Panagos Report, ¶¶44-59 and Section VI.

Common issues include: (1) whether, by presenting consumers with an FDA-approved VCD label, the manufacturer Defendants made representations and express warranties to TPPs of the "sameness" of their products to the VCDs' RLDs, and that their products were consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and were not contaminated, adulterated, and/or misbranded; (2) whether Defendants also warranted to TPPs through their websites, brochures, and other marketing or informational materials that their VCDs complied with cGMPs and did not (or were not likely to) contain any ingredients besides those identified on the products' FDA-approved labels, including genotoxic impurities such as nitrosamines; (3) whether, in conducting formulary management, TPPs and their PBMs reasonably expect that generic prescription drugs reimbursable on their formularies are legally compliant in terms of pharmaceutical equivalence, therapeutic equivalence, or bioequivalence, or are otherwise the same as their RLD counterparts; and (4) whether TPPs permitted the VCDs to be included on their formularies based on the Defendants' misrepresentations that their VCDs were generic equivalent, therapeutic equivalent, and bioequivalent to brand-named Diovan, satisfied all compendia, quality, purity, and other requirements, complied with all cGMPs, and were safe for consumption.

These central common issues predominate over any individualized issues that could arise because proving the Defendants' liability on these issues involves the same class-wide evidence. For example, whether the Defendants made representations and express warranties to TPPs that their VCDs were the same as the RLD is a matter of class-wide proof. So is whether the Defendants marketed to TPPs that their VCDs were consistent with the safety, quality, purity, identity, and strength characteristics of the RLD.

2. A class action is the superior vehicle for adjudicating this dispute and is manageable.

Rule 23(b)(3)'s superiority requirement is also satisfied. The superiority requirement seeks to ensure that a class action will "achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results." *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 615 (1997) (quotation marks omitted). In addition, "superiority" requires the Court "to balance, in terms of fairness and efficiency, the merits of a class action against those of 'alternative available methods' of adjudication." *Georgine v. Amchem Products, Inc.*, 83 F.3d 610, 632 (3d Cir. 1996), *aff'd*, 521 U.S. 591 (1997).

This action provides a single forum to adjudicate the rights of thousands of TPPs as to the same issues, and thus affords an efficient resolution to this multi-district controversy. The alternative to class certification would be wasteful, inefficient, and for the absent class members, infeasible. *In re Urethane Antitrust Litig.*, 237 F.R.D. 440, 453 (D. Kan. 2006); *In re Bromine Antitrust Litig.*, 203 F.R.D. 403, 415-16 (S.D. Ind. 2001); *In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493, 527 (S.D.N.Y. 1996). This is a classic case in which a class action is superior to the alternative of thousands of individual actions. The large size of the Class makes a class action the superior method for the fair and efficient adjudication of the controversy.

The Third Circuit has said that class actions under the laws of multiple states are manageable if the state laws can be grouped into predictable patterns. *Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 183 (3d Cir. 2014) ("[W]e [have] emphasized our willingness to certify nationwide classes where differences in state law fell 'into a limited number of predictable patterns,' and any deviations 'could be overcome at trial by grouping similar state

laws together and applying them as a unit.'"). Courts have also held that multistate class actions organized into single-state subclasses do not raise any manageability concerns. *See Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 512 (6th Cir. 2015) (affirming five single-state consumer fraud classes); *Peterson v. Costco Wholesale Co.*, 312 F.R.D. 565, 580-82 (C.D. Cal. 2016) (nine single-state subclasses overcome state law variation problems and render action manageable); *Saltzman v. Pella Corp*., 257 F.R.D. 471, 484-86 & n.12 (N.D. Ill. 2009) (six state consumer fraud subclasses); *see also Grandalski*, 767 F.3d at 183 (where "grouping proposal . . . consisted of a 'series of charts setting forth comprehensive analyses of the various states' laws potentially applicable to their common law claims,'" that "in-depth treatment justified the District Court's decision to group state laws . . . ."). Separating states into subclasses is an accepted and effective method of dealing with any material differences or manageability concerns among state laws. *See generally Reyes*, 802 F.3d at 494.

TPP Plaintiffs do not foresee any management problems in this case. Plaintiffs' Economic Loss Trial Management Plan and Structure demonstrates that both Consumer and TPP economic loss class claims can be tried as a practical matter. The manageability factor focuses on "practical problems that may render the class action format inappropriate for a particular suit." *Eisen v. Carlisle & Jacqueline*, 417 U.S. 156, 164 (1974). Denial of class certification based on "vaguely-perceived management problems" is disfavored, as it would be contrary to the policy behind Rule 23. *Yaffe v. Powers*, 454 F.2d 1362, 1365 (1st Cir. 1972).

E. The Proposed Classes and Subclasses Are Grouped by Common Issues of State Law and Fact that the Court Has Already Recognized in State Groupings in Its Orders on Motions to Dismiss.

As set forth in Plaintiffs' Motion for Class Certification, TPPs respectfully ask the Court to certify the classes and subclasses defined in detail in the motion. The subclasses are based on

state-law groupings like those the Court has already adopted in its Orders on motions to dismiss and in The Special Master Report on Plaintiffs' Motion for Leave to Amend Master Complaints, ECF No. 1614. The proposed classes below all have the same exclusions. *See* footnote 9 above.

CONCLUSION

The Court organized its opinions on the motions to dismiss and motion to amend based on similarities among various state laws. TPP Plaintiffs have followed the same principle in fashioning the class definitions contained in Plaintiffs' Motion for Class Certification. The Court should approve the class and subclass definitions because they accurately categorize class members according to predominating, common issues of law, an organizing principle that is accepted in this Circuit. *See Grandalski*, 767 F.3d at 183-84. For the foregoing reasons, Third-Party Payors respectfully request that the Court certify the proposed classes and subclasses.

Dated: November 10, 2021

Respectfully Submitted,

/s/ *Jorge Mestre*
Jorge Mestre
RIVERO MESTRE LLP
2525 Ponce de Leon Blvd., Suite 1000
Miami, FL 33134
Phone (305) 445-2500
jmestre@riveromestre.com

/s/ *Gregory P. Hansel*
Gregory P. Hansel
PRETI, FLAHERTY, BELIVEAU & PACHIOS, CHARTERED, LLP
One City Center
P.O. Box 9546
Portland, ME 04112
Phone: (207) 791-3000
ghansel@preti.com

Proposed Third-Party Payor Economic Loss Co-Lead Class Counsel

/s/ Ruben Honik
Ruben Honik
HONIK LLC
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Phone: (267) 435-1300
ruben@honiklaw.com

/s/ Daniel Nigh
Daniel Nigh
LEVIN, PAPANTONIO, THOMAS, MITCHELL RAFFERTY & PROCTOR, P.A.
316 South Baylen Street
Pensacola, FL 32502
Phone: (850) 435-7013
dnigh@levinlaw.com

/s/ Adam Slater
Adam Slater
MAZIE, SLATER, KATZ & FREEMAN, LLC
103 Eisenhower Pkwy, 2nd Flr.
Roseland, NJ 07068
Phone: (973) 228-9898
aslater@mazieslater.com

/s/ Conlee S. Whiteley
Conlee S. Whiteley
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

MDL Plaintiffs' Co-Lead Counsel

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of November 2021, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. (There are no redactions in this brief.)

/s/ *Gregory P. Hansel*
Gregory P. Hansel